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510(k) SUMMARY

AUG - 3 2007

1. Trade (Proprietary) Name

Allevyn Ag Dressings

2. Common/Classification Name

Common Name: Silver Sulfadiazine Containing Antibacterial Barrier Dressings

Classification Name: Dressing

Classification Code: FRO

3. Applicant's Name & Address

Smith & Nephew Inc
11775 Starkey Road,
PO Box 1970,
Largo, Florida,
FL 33779-1970
Phone: 727-392-1261
Fax: 727-399-3468

4. Contact Information

Terry McMahon
Regulatory Affairs Manager
Phone: 727-399-3785
Email: terry.mcmahon@smith-nephew.com

Date Prepared: 01 August 2007

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5. Device classification and Panel

A final classification for "Dressing" has not been implemented; however, a Class II classification has been proposed by the General and Plastic Surgery Devices Panel. At this time however, Classification Code FRO is unclassified.

6. Predicate devices

Allevyn Ag is similar in form and function to Acticoat Moisture Control Dressing (K050030) while being a modification of the Allevyn Foam Dressing (K963096) via the incorporation of Silver Sulfadiazine (SSD) within the absorbent foam core. Allevyn Ag has all the features and benefits associated with an absorbent foam dressing as well as the added benefit of an antibacterial barrier dressing. In-vitro testing studies showed that Allevyn Ag dressing has demonstrated to have barrier characteristics to bacterial strains: P. aeruginosa, S. aureus, E. coli, K. pneumoniae, A. calcoaceticus, S. pyogenes, E. faecalis, MRSA, C. perfringens, B. fragilis, and P. melaninogenica.

7. Performance Standards

No applicable performance standards have been established under Section 514 of the FD&C Act. Biocompatibility tests were done in conformance with relevant requirements of ANSI/AAMI/ISO-10993.

8. Indications for Use:

The Allevyn Ag Dressings are indicated for use in light to moderately exuding partial and full thickness wounds including decubitus ulcers, diabetic ulcers, 1st and 2nd degree burns, and donor sites. Allevyn Ag may be used over debrided and partial thickness wounds.

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9. Device Description

Allevyn Ag has a trilaminate structure composed of a polyurethane top film, polyurethane central Silver Sulfadiazine (SSD) containing foam pad and polyurethane perforated wound contact film. This design allows Allevyn Ag to provide continual exudate absorption and barrier protection for up to seven days, while creating and maintaining a moist wound-healing environment in a presentation that is comfortable for the patient and easy to use, apply and remove for the user.

10. Biocompatability

The biocompatibility of Allevyn Ag has been demonstrated through appropriate *in vivo* and *in vitro* tests on the foam as well as a literature review for the use of SSD. The product has been assessed in accordance with ANSI/AAMI/ISO 10993 and does not introduce any additional safety risk over the predicate devices Acticoat Moisture Control (K050030) or Allevyn Foam (K963096).

11. Summary of Substantial Equivalence[1]

Allevyn Ag is comparable to Allevyn Foam and Acticoat Moisture Control in design, materials and manufacturing methods and does not raise any additional risks in terms of safety or performance; which is supported by product specifications and testing. This is further reflected in the similar labelled indications and directions for use for that of Allevyn Ag and the predicate devices.

[1] Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without premarket approval or classification and is not to be interpreted as an admission or used as evidence in patent infringement litigation.

Date Prepared: 01 August 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2007

Smith & Nephew
% Mr. Terry McMahon
Manager Regulatory Affairs
P.O. Box 1970
11775 Starkey Road
Largo, Florida 33779-1970

Re: K063835
Trade/Device Name: Allevyn Ag Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 26, 2007
Received: June 27, 2007

Dear Mr. McMahon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

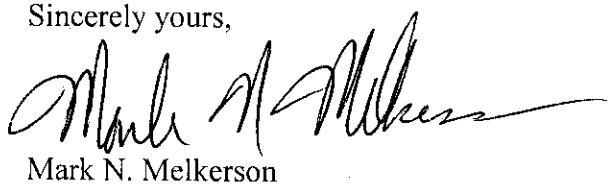
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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ALLEVYN AG DRESSING

510(k) Number: K063835

Device Name: Allevyn Ag Dressing

Indications for Use:

The Allevyn Ag Dressings are indicated for use in light to moderately exuding partial and full thickness wounds including decubitus ulcers, diabetic ulcers, 1st and 2nd degree burns, and donor sites. Allevyn Ag may be used over debrided and partial thickness wounds.

X
Prescription
(Per 21 CFR 801.109)

OR

____
Over the Counter Use

(Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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